

CLAIMS

What is claimed is:

- 5 1. A topical ophthalmic composition comprising a therapeutically effective amount of trefoil factor family peptide and a mucoadhesive component.
2. The composition of claim 1 wherein the concentration of the trefoil factor family peptide is from about 0.001% to about 1%.
3. The composition of claim 1 wherein the concentration of the trefoil factor family peptide is from about 0.01% to about 0.5%.
- 10 4. The composition of claim 1 wherein the concentration of the trefoil factor family peptide is from about 0.1% to about 0.2%.
5. The composition of claim 1 wherein the concentration of the trefoil factor family peptide is about 0.15%.
- 15 6. The composition of claim 1 which further comprises a second therapeutically active agent.
7. The composition of claim 6 wherein the second therapeutically active agent is cyclosporin A.
8. The composition of claim 1 wherein the mucoadhesive component
- 20 comprises tamarind seed polysaccharide.
9. The composition of claim 1 which comprises tamarind seed polysaccharide, about 0.5% sodium chloride, about 0.005% benzalkonium chloride, and about 0.6% of a borate buffer wherein the pH of the composition is adjusted to from about 6 to about 8.
- 25 10. A method of preventing or treating dry eye in a person comprising topically administering to the eye of said person a composition comprising a therapeutically effective amount of a trefoil factor family peptide and a mucoadhesive component.
11. The method of claim 10 wherein said mucoadhesive component
- 30 comprises an oligosaccharide or a polysaccharide.
12. The method of claim 10 wherein the concentration of the trefoil factor family peptide is from about 0.001% to about 1%.

13. The method of claim 10 wherein the concentration of the trefoil factor family peptide is from about 0.01% to about 0.5%.
14. The method of claim 10 wherein the concentration of the trefoil factor family peptide is from about 0.1% to about 0.2%.
- 5 15. The method of claim 10 wherein the concentration of the trefoil factor family peptide is about 0.15%.
16. The method of claim 10 wherein said composition further comprises a second therapeutically active agent.
17. The method of claim 16 wherein said second therapeutically active agent
10 is cyclosporin A.
18. The method of claim 11 wherein the mucoadhesive component comprises tamarind seed polysaccharide.
19. The method of claim 11 wherein said composition comprises tamarind seed polysaccharide, about 0.5% sodium chloride, about 0.005% benzalkonium
15 chloride, and about 0.6% of a borate buffer wherein the pH of the composition is adjusted to from about 6 to about 8.
20. A pharmaceutical product comprising a composition having a therapeutically effective concentration of a trefoil factor family peptide and a mucoadhesive component which is dispensed from a package suitable for
20 ophthalmic use, wherein the use of the composition for the prevention or treatment of dry eye is indicated thereon.
21. The product of claim 20 wherein the concentration of the trefoil factor family peptide is from about 0.001% to about 1%.
22. The product of claim 20 wherein the concentration of the trefoil factor
25 family peptide is from about 0.01% to about 0.5%.
23. The product of claim 20 wherein the concentration of the trefoil factor family peptide is from about 0.1% to about 0.2%.
24. The product of claim 20 wherein the concentration of the trefoil factor family peptide is about 0.15%.
- 30 25. The product of claim 20 which further comprises a second therapeutically active agent.

26. The product of claim 25 wherein the second therapeutically active agent is cyclosporin A.
27. The product of claim 20 wherein the mucoadhesive component comprises tamarind seed polysaccharide.
- 5 28. The product of claim 20 wherein said composition comprises tamarind seed polysaccharide, about 0.5% sodium chloride, about 0.005% benzalkonium chloride, and about 0.1% of a borate buffer wherein the pH of the composition is adjusted to from about 6 to about 8.
29. The composition of claim 1 wherein the trefoil family factor peptide is
10 TFF1 or TFF3.
30. The composition of claim 1 wherein the trefoil family factor peptide is TFF1.
31. The method of claim 10 wherein the trefoil family factor peptide is TFF1 or TFF3.
- 15 32. The method of claim 10 wherein the trefoil family factor peptide is TFF1.
33. The method of claim 11 wherein the trefoil family factor peptide is TFF1 or TFF3.
34. The method of claim 11 wherein the trefoil family factor peptide is
20 TFF1.
35. The product of claim 20 wherein the trefoil family factor peptide is TFF1 or TFF3.
36. The product of claim 20 wherein the trefoil family factor peptide is TFF1.
- 25 37. An aqueous composition comprising a trefoil factor family peptide and a second therapeutically active agent, wherein said composition is indicated for topical ophthalmic use in the treatment of dry eye.
38. The composition of claim 37 which further comprises a mucoadhesive.
39. The composition of claim 37 wherein said second therapeutically active
30 agent comprises a nucleotide purinergic receptor agonist; a nicotinic receptor agonist; a tetracycline or a derivative or analogue thereof, or a chemically modified tetracycline; a corticosteroid; a product of human lacrimal gland

acinar epithelia; an androgen or an analogue thereof; or a cyclosporin or a derivative thereof.

40. The composition of claim 39 wherein said second therapeutically active agent comprises a nucleotide purinergic receptor agonist.

5 41. The composition of claim 40 wherein said second therapeutically active agent comprises a uridine 5'-triphosphate, a dinucleotide, a cytidine 5'-diphosphate, an adenosine 5'-diphosphate, a P¹-(cytidine 5')-P-(uridine 5')-tetraphosphate, or a P¹, P⁴-di(uridine 5')-tetraphosphate.

10 42. The composition of claim 39 wherein said second therapeutically active agent comprises a nicotinic receptor agonist.

43. The composition of claim 42 wherein said second therapeutically active agent comprises nicotine or an analogue thereof; trans-metanicotine or an analogue thereof; epibatidine or an analogue thereof; a pyridol derivative; a piperidine alkaloid; or imidacloprid or an analogue thereof.

15 44. The composition of claim 39 wherein said second therapeutically active agent comprises a tetracycline, a derivative or analogue of tetracycline, or a chemically modified tetracycline.

45. The composition of claim 39 wherein said second therapeutically active agent comprises a corticosteroid.

20 46. The composition of claim 45 wherein said second therapeutically active agent comprises methylprednisolone sodium succinate, prednisolone acetate, prednisolone sodium phosphate, fluorometholone, fluorometholone acetate, dexamethasone sodium phosphate, hydroxymethyl-progesterone, rimexolane, budesonide, or tixocortol pivalatein.

25 47. The composition of claim 39 wherein said second therapeutically active agent comprises a product of human lacrimal gland acinar epithelia.

48. The composition of claim 47 wherein said second therapeutically active agent comprises transforming growth factor beta.

30 49. The composition of claim 39 wherein said second therapeutically active agent comprises an androgen, or an androgen analogue.

50. The composition of claim 49 wherein said second therapeutically active agent comprises 17 α -methyl-17 β -hydroxy-2-oxa-5 α -androstane-3-one;

testosterone or a derivative thereof; 4,5 α -dihydrotestosterone or a derivative thereof; 17 β -hydroxy-5 α -androstane or a derivative thereof; 19-nortestosterone or a derivative thereof; or a nitrogen-substituted androgen.

51. The composition of claim 39 wherein said second therapeutically active
5 agent comprises a cyclosporin or a cyclosporin derivative.

52. The composition of claim 51 wherein said second therapeutically active agent comprises cyclosporin A, cyclosporin B, cyclosporin C, cyclosporin D, or cyclosporin G.

53. The composition of claim 51 wherein said second therapeutically active
10 agent comprises cyclosporin A.